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REMARKS

Claims 131-191 are pending. Applicants have hereinabove amended claim 187 to correct its dependency from claim 172.

Restriction Requirement Under 35 U.S.C. §§121 and 372

In the April 4, 2008 Office Action, the Examiner imposed a restriction requirement under 35 U.S.C. §121 of the claims among the following five (5) allegedly independent and distinct inventions:

- I. Claims 131-171 drawn to the method of inducing formation of blood vessels comprising administering an enriched population of cells that express the marker Stro-1.
- II. Claims 131-171 drawn to the method of inducing repair of blood vessels comprising administering an enriched population of cells that express the marker Stro-1.
- III. Claims 172, 175-181 and 183-186 drawn to the method of inducing formation of blood vessels comprising administering a cultured or expanded enriched population of cells that express the marker Stro-1.
- IV. Claims 172, 175-181 and 183-186 drawn to the method of inducing repair of blood vessels comprising administering a cultured or expanded enriched population of cells that express the marker Stro-1.
- V. Claims 173-174, 182 and 187-191 drawn to the method of inducing formation of blood vessels in a patient suffering from disease associated with loss of alpha smooth muscle actin from vasculature comprising administering a cultured or expanded enriched population of cells that express the marker Stro-1.

The Examiner asserted that the application contains inventions which are not so linked as to form a single general inventive

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concept under PCT Rule 13.1. The Examiner asserted that the invention in claim 131-191 do not relate to a single general inventive concept under PCT Rule 13.2 because the general technical feature "utilization of MPCs (Stro-1<sup>+</sup> cells in vascular repair) in tissue repair that links the invention has been described in the prior art (e.g. Dennis et al., Cells Tissues Organs, 2002; 170-73-82 and Hoerstrup et al., Circulation, 2002; 106(Suppl):I143-I150)."

In response to this restriction requirement, applicants hereby elect, with traverse, to prosecute the invention of the Examiner's claim Group III, i.e. claims 172, 175-181 and 183-186, drawn to a method of inducing formation of blood vessels comprising administering a cultured or expanded enriched population of cells that express the marker Stro-1.

Applicants note that the Examiner stated that claim 187 is improper as it depends on itself. In response, applicants have hereinabove amended claim 187 to correct its dependency from claim 172. Accordingly, applicants understands that amended claim 187 and its dependent claims 188-191, which were "tentatively" categorized by the Examiner as part of claim Group V, also fall within elected claim Group III.

In addition, in response to the Examiner's species election requirement on pages 3-5 of the Office Action, applicant hereby elects, with traverse, the following species, as lettered in the April 4, 2008 Office Action, for prosecution on the merits:

- L. to repair existing blood vessels,
- M. 1% MPC,
- N. 1% STRO-bright MPCs,
- P. adipose tissue,

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Q. 1% MPC, and

R. 1% STRO-bright MPCs.

Applicants traverse the requirement for restriction on the basis that the claims do have a common inventive concept in compliance with PCT Rule 13.1. Applicants note in regard to this that pursuant to 37 C.F.R. §1.499, Rule 13.1 governs restriction practice in the subject national stage application filed under 35 U.S.C. §371.

Applicants submit that the premise of the Examiner's Restriction Requirement is that the general technical feature that forms the basis of the invention is the utilization of Stro-1<sup>+</sup> MPCs in tissue repair, and that this feature has been disclosed in the prior art (namely Dennis et al. (2002), and Hoerstrup et al. (2002)). However, applicants note that the special technical feature linking these claims is not simply the utilization of Stro-1<sup>+</sup> MPCs in tissue repair, but the specific application of Stro-1<sup>+</sup> cells in the formation or repair of **blood vessels** in a target tissue of a patient.

In addition, neither of the citations raised by the Examiner discloses the use of Stro-1<sup>+</sup> cells in repair of blood vessels. Dennis et al. (2002) describes differentiation of Stro-1<sup>+</sup> cells in adipocytes, chondrocytes and osteoblasts. There is no mention in this publication of the use of Stro-1<sup>+</sup> cells for the repair or formation of blood vessels. Hoerstrup et al. (2002) describes the use of human MSCs to generate tissue engineered heart valve. There is no mention in this paper that the MSCs are Stro-1<sup>+</sup>. Accordingly, applicants request withdrawal of this restriction requirement on the basis that the claims are all linked by a novel and non-obvious general technical feature.

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Applicant further notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction requirement be withdrawn in view of the fact that the claims of Groups I-V are not independent.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect....". The claims of Group I-V are related in that they are drawn to similar methods of use. All of the methods relate to inducing formation or repair of blood vessels in a target tissue of a patient.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of prior

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art with regard to any of Groups I-V would identify art for the other Groups. In particular, a search of prior art for Group III would likely overlap with a search for Group IV.

Since there is no serious burden on the Examiner to examine Groups I-V in the subject application, the Examiner should examine the entire application on the merits.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine the pending claims on the merits.